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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,869

07/18/2003

Suresh K. Tikoo

293102003600

2929

25226 7590 10/08/2008
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/622,869	Applicant(s) TIKOO, SURESH K.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-26, 28-55 and 58-73 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5, 7, 10, 16, 28, 40-55 and 58-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 9, 11, 15, 17, 20, 22-25, 29, 30, 32, 33, 35, 37, 39, 65-68, 70 and 72 is/are rejected.
- 7) ☒ Claim(s) 2, 6, 12-14, 18, 19, 21, 26, 31, 34, 36, 38, 69, 71 and 73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 and 22 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendment filed July 22, 2008 is acknowledged and entered. Claims 1-3, 5-26, 28-55, 58-64 and new claims 65-73 are pending. Claims 3, 5, 7, 10, 16, 28, 40-55 and 58-64 remain withdrawn from consideration being drawn to non-elected subject matter. The elected invention is Group IV, with respect to motif TATTTTTT and SEQ ID NO: 8 (GGGTGTATTTTTTCCCCTCA). Claims 1, 2, 6, 8, 9, 11-15, 17-26, 29-39 and new claims 65-73 are under examination. All objection(s)/rejection(s) over cancelled claims are moot.

Response to Amendment

2. The following objection(s)/rejection(s) are withdrawn:
- The rejection of claims 29, 31 and 32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell, wherein the cell is isolated, purified or cultured, does not reasonably provide enablement for a host cell comprised within a living organism such as a transgenic animal or human, is withdrawn in view of Applicant's amendment. (Note that claim 30 remains rejected, see below.)
 - The rejection of claims 26, 27, 30, 32, 34, 36, 38, 39 and 57 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of Applicant's amendment or moot in view of cancelled claims.
 - The rejection of claims 1, 2, 4, 6, 8, 9, 11, 15, 17, 29, 31, 33, 35, 37, 38, 39 and 56 under 35 U.S.C. 102(b) as being anticipated by Reddy *et al.* (WO 99/53047, "Reddy") is withdrawn in view of Applicant's amendment, or moot in view of cancelled claims. The claims as amended indicate that the encapsidation sequence is within nucleotides 212-531 of PAV3. Reddy's disclosure of the complete nucleotide sequence of the genome of

PAV3, which inherently contains TATTTTTT and SEQ ID NO: 8 (abstract), does not teach or suggest the particular portion of the PAV3 genome to which the claims are now limited to.

- The rejection of claims 1, 2 and 6 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-17 and 19-23 of U.S. Patent No. 6,492,343, is withdrawn in view of Applicant's amendment. The patented claims require the presence of a PAV3 genome, however, the instant claims are now limited to a region of nucleotides 212-531 of the PAV3 genome.

Claims Summary

3. The claims are drawn to an isolated porcine adenovirus (PAV) sequence essential for encapsidating an adenovirus genome (inserting adenovirus DNA into adenovirus capsids). As amended, the claims indicate that the encapsidation sequence consists of a nucleotide sequence between nt 212-531 of porcine adenovirus type 3, and that the sequence comprises elected motif TATTTTTT. While Applicant may intend for the newly introduced claim language to limit the encapsidation sequence to a sequence that contains nt 212-531, the recitation of "a nucleotide sequence between nt 212 and 531" allows for any fragment within 212-531.

The sequence comprises TATTTTTT, which is derived from PAV3 and presumed to be present in any PAV3 genome. Specifically, the sequence comprises SEQ ID NO: 8, also derived from PAV3 and is also presumed to be naturally present in any PAV3 genome. Also claimed are vectors, specifically, replication-defective vectors comprising heterologous encapsidation sequences and inverted terminal repeat sequences from human adenovirus or bovine adenovirus. The vector also comprises at least one nucleic acid sequence encoding a transgene, and the

vector has a deletion in a nucleic acid sequence encoding an adenovirus protein. The transgene encodes an immunogenic polypeptide, an antigen of a pathogen (human, bovine, porcine, etc.).

In another embodiment, the recombinant PAV vector comprises a deletion of a sequence essential for encapsidation, specifically, TATTTTTT. (The specification discloses that packaging motifs of PAV3 appear to be functionally redundant, meaning that one or more encapsidation sequences can be deleted and viral DNA can still be encapsidated. The specification teaches that some of them alone can support the viral packaging and make PAV viable (page 6, paragraph [0054]).)

Also claimed are viral particles comprising the vectors, host cells comprising the vectors, and compositions comprising the vectors with a pharmaceutically acceptable carrier or excipient. The compositions are capable of inducing a humoral, cell-mediated or mucosal immune response in a mammalian subject. The mammal is a swine, bovine, canine or human. The vector further comprises a nucleotide sequence encodes a native or recombinant antigenic peptide from human, swine or bovine pathogens.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 32 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell, wherein the cell is isolated, purified or cultured, does not reasonably provide enablement for a host cell comprised within a living organism such as a transgenic animal or human, for reasons of record. Applicant indicates that

the rejection of claim 30 is overcome because claim 29 has been amended to recite "isolated host cell". However, claim 30 is not dependent on claim 29. Correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 remains rejected under 35 U.S.C. 102(a) as being anticipated by Nielsen *et al.* (US 6,350,853, "Nielsen"). The claim is summarized above. Based on the interpretation of the claim as outlined above, the Nielsen disclosure still anticipates the instantly claimed embodiment. The Nielsen reference discloses a sequence of 10 nucleotides that contains TATTTTTT (see Nielsen's SEQ ID NO: 4). Although Nielsen does not disclose SEQ ID NO: 4 as a PAV3 sequence essential for encapsidation, the claims are drawn to products, regardless of the name, origin or function assigned to it. Therefore, Nielsen's sequence anticipates Applicant's invention as claimed in claim 1.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 9, 11, 15, 17, 20, 22-25, 29, 33, 35, 37, 39, 65-68, 70 and 72 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-17 and 19-23 of U.S. Patent No. 6,492,343. Note that claim 15 was erroneously omitted from the rejection in the Office action of January 22, 2008, but is now included in the rejection, as are newly presented claims 65-68, 70 and 72. Applicant requests that the rejection be held in abeyance until allowable subject matter is indicated.

Conclusion

7. Claims 2, 6, 12-14, 18, 19, 21, 26, 31, 34, 36, 38, 69, 71 and 73 are objected to for being dependent on rejected claims, but would otherwise be allowable with regard to the elected species if rewritten in independent form.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off,. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, Art Unit 1648